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Titel: Nurse-led interventions in the concept of Randomised Controlled Trials

- Critical perspectives on how to handle social contexts

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Abstract: This article focuses on the randomised clinical trial (RCT) as research method in nursing interventions and problematises its methodological ability and delimitations considering the extensive use of this method in the healthcare system. The article aims to examine *if* and *how* RCT in nurse-led interventions are handling questions concerned with contextual influences and discusses the outcome. A systematic literature review was conducted, consisting of 55 RCT from 2006–2010. The results show: all interventions were placed in a social arena and address interactions but did not incorporate or reflect the meaning and importance of the social context in the design; altogether made recommendations for interventions leading to implementation of profound changes in clinical practices; or, if not, then the existing control intervention is assumed to be the best current intervention. Meaning that RCT operates as if no contextual impact exists, and at the same time, make claims to guide and change actions in the clinical practice. This has implications for the understanding of Evidence-based nursing according to the Evidence Hierarchy. Further discussion concerning RCT design and impact in clinical practices are called for.

Introduction

In 1948, the modern concept of RCT was developed (Christensen 1999; Lilienfeld 1982). Today, RCTs is a frequently used method amongst all healthcare professionals in the medical field; ranging from testing medicine on patients to testing other forms of interventions in the medical clinic, such as psychological interventions, educational interventions and nursing interventions. An outcome of this historical movement in research is that nursing care is assumed to contribute evidence in the same way as required in the medical research tradition. It means that there today is a strong research claim for nurse-designed studies using RCT involving a focus on clinical care (Heyman 1995; Pravikoff, Tanner & Pierce 2005; Pruitt & Privette 2001; Petersen 1998). The RCT is considered to be 'the golden standard' for evaluating the effectiveness of interventions; the preconception is that RCT works in evidence-informed policy making and in practice (Torgerson & Torgerson 2008). Thus, there is an underlying understanding or assumption that a practice in clinical medicine is not judged to be sufficiently justified if not tested through an RCT (Doll 1982; Glasdam 2003).

The RCT as a research design and method is grounded on epistemological and ontological assumptions and developed into a specific research paradigms, as many other research methods are. The RCT methodology rests on principles delineated in the positivistic paradigm research tradition forming the basis of the understanding of the so-called Evidence-based medicine. Evidence-based medicine has been described as an integration of best research evidence, clinical expertise, and patient values (Sackett, Strauss, Richardson, Rosenberg & Haynes 2000).

Evidence-based medicine was expanded to Evidence-based Practice (EBP) to accommodate other professions than medicine. Based on the work of the US Agency for Healthcare Research and Quality in 1992, the Evidence Hierarchy of Study Types has been an accepted system for grading guideline recommendations in Evidence-based medicine and Evidence-based Nursing. Systematic reviews and meta-analyses of RCT are placed at the top of this Evidence Hierarchy; RCT is placed second highest. At the bottom of the hierarchy are non-experimental studies and expert opinions (Guyatt et al 1995). This Evidence hierarchy is widely accepted in the international medical field, and also in nursing research, even though concerns have been raised concerning the RCTs. These concerns are of a philosophical nature, such as when it is taken for granted that the results from the study in 'the laboratory' or other 'constructed contexts' per se are assumed to become transformed and guide changes in practice involving people's health, well-being and approaches related to their life-world (Christensen 1999; Glasdam 2003; Jensen 2004; Martinsen & Boge 2004; Martinsen 2009). Further, researchers have argued that these concerns are also of a methodological and an epistemological nature. The main reason is that the concept of RCT presupposes a fundamental condition based on a premise of constants and therefore disregards or even excludes the impact of changeable social and contextual influences (Christensen 1999; Hansen & Tjoernhoej-Thomsen 2012). The RCT also states variables to be selected and defined a priori in order to address the corresponding objectives of the study, in order to enhance the reliability and validity of the eventual findings through statistical calculations and statistical significance (Thelle 2004).

Many results from RCTs based on interactional nurse-led interventions are published (Vedelö & Lomborg 2011), but only a few researchers have until now addressed the contextual impacts in relational-based intervention projects (Berk 2005; Coates 2010). This paper is concerned with how the

RCTs handle these circumstances when it comes to interventions that consist of interactions between human beings, and how the methodological and epistemological issues related with conceptuality are critically reflected upon in the vast amount of studies based on RCT. Our assumption is that healthcare research has a tendency to over-simplify, by assuming that all contextual variables and outcomes can be controlled in studies in clinical practice as was the case in the 'laboratory'. Further, researchers have pointed out that it is not possible, even in a carefully planned study, to predict the impact that external influences may have on the subject (Coates 2012). Therefore, this paper focuses on the randomised clinical trial (RCT) as a research method in nursing interventions and problematises its methodological ability and delimitations considering the extensive use of this method in the healthcare system. The aim of this paper is to explore if and how studies are handling questions concerned with contextual influences, by re-doing a systematic literature review on literature used in an already published literature study (Fridlund et al 2014) in which two of the authors of this study took part. . Also, this present study aims to contribute to the debate and discussion of the importance of considering the contextual and relational influences in research focussing on intervention-based studies, RCTs; Further, we problematize the ontological claim in RCT-based research, that is, the ontological assumption of a constant in intervention programmes or strategies which is invariant in different settings. This study also aims to contribute to reflections on epistemological issues concerning with RCT as designated by researchers in the medical field being the preferable research method in nursing, which is leading to that RCT-based research in present time is meant to guide the complex (clinical) healthcare practices through its results.

Method

The interest in conducting this study emerged [from a](#) systematic literature review conducted in 2011 involving RCT-designed interventions in somatic adult healthcare contexts (Fridlund et al 2014). It became notable that the included RCT studies in general did not consider the contextual influences. We found it interesting to explore this further, by focusing more explicit on if any considerations were taken to contextual influences. The present study is re-analysing the data of the former literature review of Fridlund et al. (2014). Our literature review analysis uses the same data/studies as Fridlund et al (2014), but we have different aims, and we explore if and how the studies are handling questions concerned with contextual influences in nurse-led RCT interventions.

Inclusion and Exclusion Criteria

The literature search was carried out with a primary criterion of including studies with a focus on nurse led interventions concerning adults in somatic healthcare (Fridlund et al 2014). Specific inclusion criteria were: nurse-led RCTs concerning caring actions in adult patients in somatic healthcare; evaluating caring actions and articles not older than five years (2006-2010).

Exclusion criteria were: psychiatric healthcare; women's health; children (<18 years); low quality of the study according to The Swedish Council on Health Technology Assessment's well-established audit template (Statens beredning för medicinsk utvärdering 2010). Women's health is excluded because it includes both somatic and mental health, and also delivery of babies and issues related to children (Fridlund et al 2014).

The Literature Search and Studies included

The International databases PubMed/Medline and CINAHL were used to search literature in English, produced between 2006 and 2010. Both controlled vocabulary (Medical Subject Headings [MeSH]) and free-text words were used. The MeSH-terms were “Nurse Clinicians” OR “Nurse Practitioners” and the free-text words were nurse specialist, nurse practitioner, nurse-led and nurse-managed. The literature search also excluded the following free text words from the search: gynecology, pediatrics, pregnancy and psychiatric. In total, 244 references were found and 55 studies (marked with asterisks in the reference list) were included in the study (Figure 1) (Fridlund et al 2014).

Analysis Strategy

First, all the articles we found were read and tabulated, one by one for this study. Questions of importance when exploring the aims of this study were: What are the contexts of care; what is the Intervention about; who were together, where and how and why; how are the results of the intervention measured? The articles were all reviewed by two of the authors. Second, each review was discussed together with the third author, aiming at identifying and not missing out any aspects mentioned about the social context in which the studies were performed. Finally, the authors compared the studies across all data by posing the same questions when analysing each article.

Results

All included studies were based on randomisation between two or three arms, where the concept of the experimental intervention(s) was described in all studies. The concept of the control arms was described in 38 studies, but unspecified and only stated as “usual practice/usual care” in 17 studies (Table 1). This could be illustrated by the study of Goessens et al (2006):

“Patients were randomized [,,,] to either nurse practitioner care plus usual care (intervention group) or usual care alone (control group)”
(Goessens et al 2006: p.997).

They do not describe ‘usual care’ explicitly in the article, only the overall components in ‘nurse practitioner care’ (intervention):

“At the first visit, patients were told about their vascular risk factors and individualized, realistic goals were set in co-operation with the patients. Action plans were made for lifestyle changes: smoking cessation, regular exercise, healthy diets, and medical treatment of risk factors (antiplatelet agents, blood pressure, lipid, and glucose-lowering agents, or folic acid)..... ” (Goessens et al 2006: p.997).

The issue is that the elements of the intervention programme maybe interfere with ‘care as usual’ since we know nothing about that. However, the description of the elements of the intervention is often included in care as usual and the outcome of the intervention might be problematic or even uncertain.

All interventions were placed in a social context (healthcare activity of some kind), either at hospitals (nine studies), professional settings outside hospitals (ten studies), private homes of the patients (seven studies), telephone- and web meetings (19 studies), or combinations of those contexts (ten studies). All interventions addressed interactions between at least one nurse and one patient. Further, all intervention in the studies were

evaluated by quantitative measurement taking into account the patient as a sole actor and nine of these studies also measured on cost-benefit of the intervention. Again the study of Goessens et al (2006) could serve as an example:

”At both follow-up evaluations, data were collected on current medication use and smoking behavior. The vascular risk factor levels were again determined by physical examination and a fasting blood sample. Quality of life was assessed by the Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36) [...]. The primary outcome was the cardiovascular risk profile at 1 year after randomization. We measured change in risk factors and medication usage. The proportion of achieved treatment goals for each risk factor before and after the intervention was compared for the intervention and the control group” (Ibid: p.998).

Thus the nurse is an active part in above mentioned intervention in the study of Goessens et al’s (2006) and interacts with the patient (s)he is not regarded as a part or a component of the evaluation concept of the intervention. None of the studies evaluated the professionals, nor their mutual interactions, and consequently left out issues concerned with the way social influences might have impact on the intervention (Table 1). Nor the place of intervention is pointed out as significant for or as an evaluation parameter for the outcome of the intervention in the study of Goessens et al’s (2006). It became clear that none of the studies in this literature review evaluate the social contexts’ influence and impact on the intervention (Table 1). Nor did any of the studies evaluate the interaction between those involved in the health activity and how the interaction(s) influenced and impacted on the intervention. Taking all into consideration, none of the studies included, incorporated or reflected on the meaning and importance of contextual aspects in the study design or consequently in the evaluation of the studies. These social arenas, social actors and

interactions were regarded as insignificant constants in RCT. All studies made recommendations, based on their results, either for experimental interventions representing profound changes for implementation in daily clinical practices, or, that the existing (control) intervention is assumed to be the best current intervention, for example: *“In conclusion, our findings show that care provided by a nurse practitioner, in addition to usual care and on top of a vascular screening and prevention program, improved the management of important risk factors in patients with a recent clinical manifestation of a vascular disease. Adequately managed risk factors will contribute to a reduction in vascular morbidity and mortality in this group of high-risk patients”* (Goessens et al 2006: p1002).

Discussion

In this section, we discuss our results in relation to the importance of a social dimension when humans act together. Further we reflect the fact that the studies in this systematic literature review operate as if non-contextual impact exists, and at the same time make claims that experimental or controlled interventions from the studies should be implemented or further developed in clinical healthcare practices, for example in various health activities. Also, we reflect on the absence of consideration of social dimensions in the studies included in this review in relation to the discourse of evidence-based nursing in theoretical and clinical nursing. Finally, we reflect on the method used in our study. When we discuss the social context it should be considered on an abstract level since the issue here is not to discuss the complexity of these contexts per se.

The studies included in this systematic literature review handle the social context(s) and interactions in an unproblematic, unreflected way, as if

they were insignificant constants. As the chosen example of the study of Goosen et al (2006) showed, the meeting between nurse and patient took place in a specific social context with an interaction between two persons. Such a communicative interaction probably has an influence on the given information, the way the information is received and interpreted in the care action plan and how this plan is applied into action by the patient. In general, the included studies do not regard social conditions in terms of dynamic movements or interactive with other factors considered in the studies. The humans present in the experimental situation and what humans do together in the concrete situation are therefore disregarded and treated in a somewhat instrumentalist and reductionist way. This is not the case in for example life-world research traditions, also frequently used in healthcare research (e.g. McCloud, Harrington & Kin 2012; Thomas 2005), such as in phenomenology and hermeneutics, where the social interactions between humans are essential and central (e.g. Gadamer 2004a,2004b; Husserl 2002; Merleau-Ponty 1994). In addition, the social constructivists and post-structuralistic research traditions (e.g. Berger & Luckmann 1966; Bourdieu 1999; Giddens 1991) focus on social contexts, concerned with the impact of social-political discourses influences, emphasising how we experience illness, diseases or construct coping strategies. These research traditions' ontological and epistemological approaches argue in favour of the importance of contextual and relational influences, and these approaches are also often used in healthcare research (e.g. Glasdam 2003; Hardcastle, Usher KJ & Holmes 2005; Raunkiaer 2007). The life-world and everyday situation, as experienced, is not considered to be constructed solely by the person, or imposed upon her, but rather it is constituted as an internal relationship between the experiencing subject and influences of the surrounding external social context (Marton & Booth, 1997; Vygotsky, 1978).

All the RCT studies in this review, illustrated by the chosen example of the study of Gooesen et al (2006), evaluate their success on the outcomes of the patients included in the intervention, without knowing or stating what actually affected the benefits of the intervention. The studies consist of several components of the intervention and it is unclear how these inter-relate. Contrary to previously mentioned philosophers and researchers, who argue for the importance of various relationships as being essential to the intervention itself, the implementation of the experimental and control interventions make the opposite and rules out the circumstances and processes, which have been left aside as unimportant (Damschroeder et al 2009; Nielsen, Fredslund, Christensen & Albertsen 2006; Hansen & Tjoernhoej-Thomsen 2011,2012). It is reasonable to raise questions, concerning the importance of the social dimension considering it is not taken into account in RCT research since not involving any kind of acknowledging about the interaction between patients and nurses or other healthcare professionals. We argue in favour of that healthcare research using RCT design should become contextual aware of the importance of relationships. Furthermore, if the outcomes of the studies should serve as a basis for changing or not changing clinical healthcare practices, the inclusion of social contextual factors is a necessary presumption, for the validation of results. Contextual changes and variations should be dealt with and not be treated as unimportant or non-existent; at least outlined as distinct delimitations when not dealt within the RCT designed studies.

From our reasoning follows that RCTs operate as if no contextual impacts exist and at the same time the studies consider that the addressed health activity has as its core element the encounter between humans. All the studies, and in the section of results illustrated by the study of Gooesen et al (2006), claim that by using RCT this can *per se* justify interventions from the studies as sufficient or insufficient; and that the

evaluations of the interventions claim validity for recommending implementation of change versus maintenance of the status quo in clinical healthcare practice (activity). This assertion could be regarded as a problematic ontological issue. The concept of 'care/treatment as usual' is problematic as a reference to a baseline. Firstly, 'care/treatment as usual' vary in content between different healthcare settings (hospitals, primary health care centres, care in municipalities), but still outcome recommendations are given in general without considering this variation. Secondly, it is problematic to refer to 'care/treatment as usual' without in detail describe the content and how it differ from the components of the intervention programme. If this is not done we do not know the operative component of a measured effect in the outcome of an intervention. The analysis of the included studies showed a problematic vagueness in respect of these two aspects of the use of concept 'as usual'.

An intervention, *per se*, usually aims to change something and can be defined as an intentional 'change strategy' (Fraser, Richman, Galinsky & Day 2009); or argue in favour of not changing, as a way of maintaining the 'best' preference. For that reason, the intentional meaning and the contextual and relational influences concerning the social aspects must be considered when setting objectives for measurement of changes. The interventions always take place in relation to health activity and include interaction between humans. The complexity cannot be organised or treated as a fixed entity, that is, as a standardised procedure where a given input generates a given output. Consider, it is not possible to create a teaching and learning situation where every teacher (here the nurses) teaches the same content in the same way and that every student (here the patient) learns and make sense in a similar way (Marton & Booth, 1997). Circumstances such as our history (Gadamer 2004a, 2004b), backgrounds, societal history, personal experiences and preconceptions (Bourdieu 1984,1999), the people with whom we interact, and our

specific life circumstances at the moment the interventions is carried out, have an essential influence on how things turn out. These circumstances should be taken into consideration in any social intervention implemented and evaluated in clinical healthcare practice(s) before it can be regarded as a valid result and thereby become significant for those involved in the situation. Thus, it is difficult to provide an identical social intervention programme because human acting and interaction are always rooted in attitude formation, social contexts and histories (Bourdieu, 1984; Gadamer, 2004b; Glasdam 2003; Hansen & Tjoernhoej-Thomsen 2012; Krogstrup 2011). The challenge is to consider the importance of contextual influences in relation to RCT conducted studies results. Particular when far-reaching implication from RCT studies are made in terms of changing interventions and routines in healthcare practices. In research as well as in clinical interventions, we must acknowledge variations rather than treat the context from which we collect out data (as in RCT based research) in an instrumentalist way, as constant.

Firstly, the lack of consideration of the social aspects, secondly, the rationale that is based on the notion of fixed constants and defined variables (see Kendall 2003) in the analysed studies in this literature review of RCTs is an issue worth to discuss. This has some implications for the understanding of Evidence-based nursing according to the Evidence Hierarchy (Guyatt et al 1995). In the medical understanding of Evidence-based nursing, the RCTs rank highest as evidence and are designed to create the guidelines for Evidence-based practice. This is despite the fact that research based on RCTs with negative results is often excluded in the formation of evidence due to publication difficulties (Dimick, Diener-West & Lipsett 2001; Jaarsma et al 2008). All the studies in our literature review are assigned the power to define and guide the actions in clinical practices, without considering the importance of the social context in that very same practice. We find it justifiable to debate the power

RCT studies have in contemporary nursing research and how evident RCTs studies actually are, considering this lack of consideration of the social contexts impact. And what consequences will it have for patients if we build our clinical nursing practice (or any health activity) based on these RCT results? At best nothing happens, at worst the results are misleading and could do harm to patients.

Finally, we discuss the literature review method in the light of the assessment of the studies as low-middle-high quality according to The Swedish Council on Health Technology Assessment's well-established audit template (Statens beredning för medicinsk utvärdering 2010). Many factors are assessed in this template, aiming to guarantee an overall quality in a study. One or more factors can be marked with low quality, and still the overall outcome can be assessed as middle or high quality. The view developed in this article is that all of the studies included in the literature review alternatively might be regarded as having a low quality since none of them deals with the variables of social contexts and actors. Looking at other reviews and anthropological studies of RCT (e.g. Glasdam, Timm & Vittrup 2010, Dickson et al 2013, Tjoernhoej-Thomsen & Hansen 2013), many other methods or tools are proposed to measure the quality of research not taken into account in the studies included in our analysis.

Conclusion

The results of this systematic literature review show that the RCTs handle the contextual dimension, understood as interactions between humans and the contextual influencing aspects at hand, in which the experimental and controlled interventions takes place, as if non-interactiveness or contextual impact exists. In other words, the studies treat the complex social context in terms of constants. All studies give

recommendations based on their results; either the experimental interventions are supposed leading to implementation of profound changes in daily clinical practices, or the existing (control) intervention is assumed to be the best current intervention. This must have implications for the understanding of Evidence-based nursing according to the Evidence Hierarchy. Paradoxically, the RCTs operate as if no contextual impact exists, and at the same time it is considered that the very same practice has as its core element the encounter between humans and emphasises the relational and contextual. By failing to deal with presumed influences and conditions from a methodological research perspective, in ignoring and not acknowledging 'contextual movements', healthcare research has a tendency to over-simplify by the use of variables as fixed entities and as constants. An important assumption in this review is that a social context and a social interaction should be taken into consideration and a more critical stance should be taken in clinical healthcare based on RCT research and their outcomes in the form of evaluation of interventions. If the large amount of supported RCT research is to continue to guide and direct clinical practice, with a continuing high impact on the healthcare practice of today, then, a critical reflection concerning the lack of consideration about the contextual movements must come to the fore and be debated from an ontological, an epistemological and a clinical, practical perspective. The RCT design consequently is suggested to become further analysed and discussed in terms of delimitations and force of predictability, generalisability, and changeable impact in clinical practices. We argue in favour of further RCT research on social interventions should be combined, in other words mixed methods should be applied, such as including anthropological field studies and other kind of qualitative research approaches. If recommendations are made for changes, there is a need for exploring the social complexity in which the RCT are placed to gain more knowledge about what works, how it works and in which context it works.

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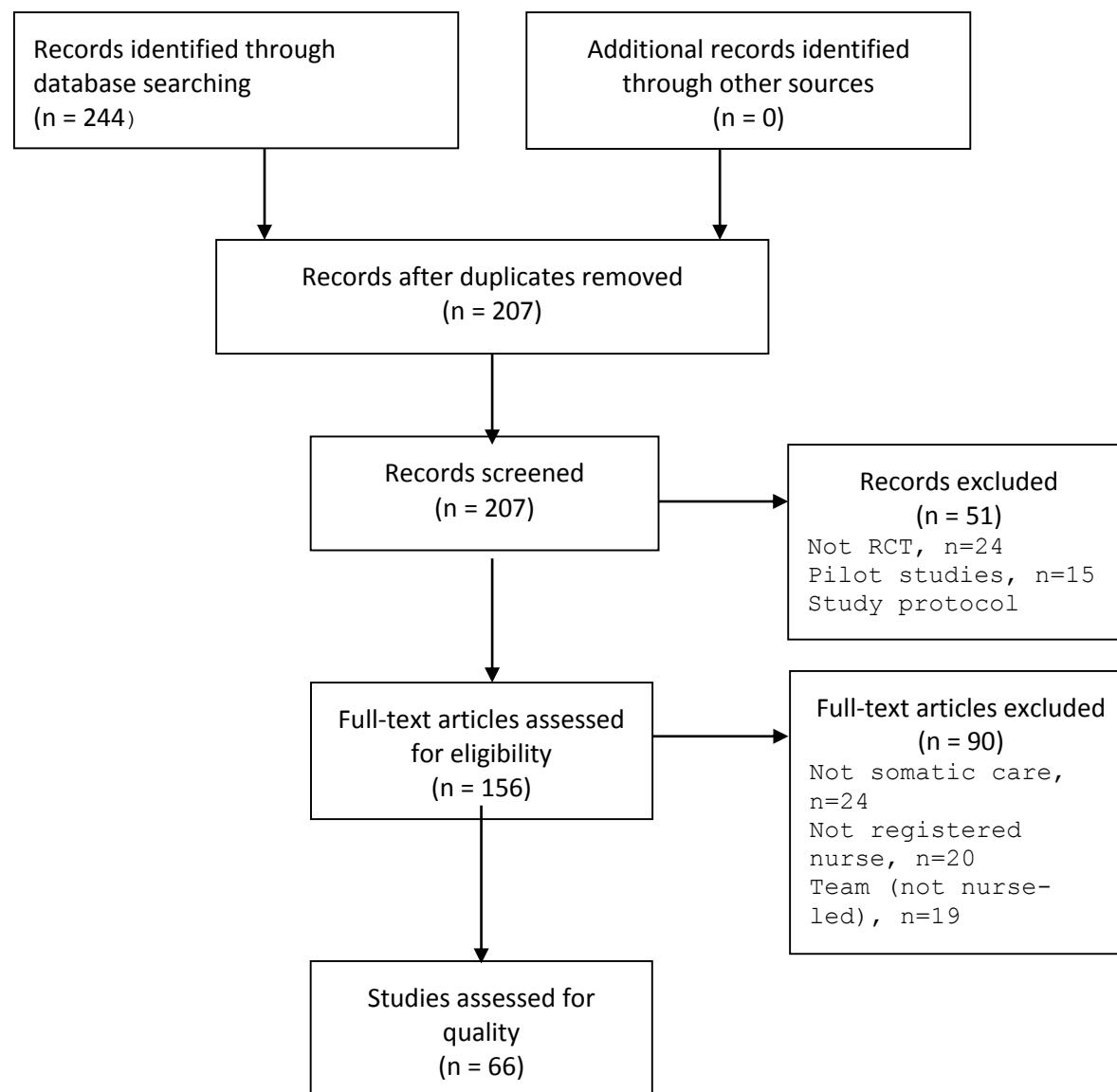
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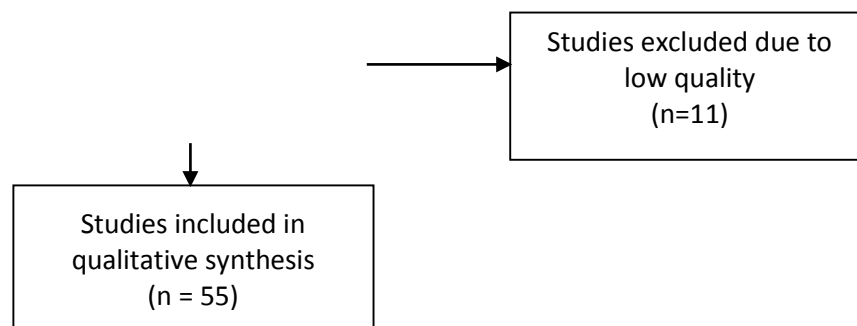
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Figur 1 Flow diagram of the systematic review process

Table 1 Descriptive overview of the studies included (n=55); context, interventions, place, participants, main content, main goal, and measurements

Authors, year, country	Intervention and control groups	Place for the intervention	Particip ants in the social interacti ons	Main Content	Main Goal	Measurements
Leimig et al. 2008, USA	Video conference health follow-up vs usual (unspecified) procedure	Interactive session between clinic and the home of the patient	Nurse and one patient	Transplant outcomes (infections, rejections, hospitalizati ons)	Detection	Blood tests, review of medication, physical assessment, transplant outcomes
Cuthbert son et al. 2009, UK	Follow-up physical rehabilitation intervention vs unspecified standard care	Hospitals	One nurse and one patient	Follow-up	QoL, cost- benefit	Short Form 36 (SH-36), Quality Adjusted Life Years (QALY's), Davidson Trauma Score, Hospital Anxiety and Depression Scale (HADS), APACHE II severity of illness and Comorbidity, Intensive Care Experience (ICE score)
Franzén et al. 2009, Sweden	Telephone follow-up vs none	Telephone	One nurse and one patient	Advice	QoL	Abbreviated Injury Scale (AIS), EuroQoL (EQ-5D)
Marcant onio et	Delirium abatement programme vs.	Skilled nursing facilities in a	Nurse, patient	Symptom managemen	Treatment and	Charlson Scale, Activities of Daily Living Scale, Minimum Data Set (MDS) 2.0.

al. 2010, USA	unspecified usual care	metropolitan region	(and family)	t	prevention	assessment
Lapointe et al. 2006, Canada	Telephone follow-up programme by hospital nurse vs usual (unspecified) control by GP	Telephone	One nurse and one patient	Follow-up, education, treatment of risk factors	Treatment, prevention, self-care, lifestyle changes, QoL, cost-benefit	Lipids, time spend with nurse management, Medical Outcomes Study 36-item Short Form (SF-36), medication
Mittag et al. 2006, Germany	Telephone counseling and information in written vs information in written	Telephone	One nurse and one patient	Counselling , support	Self-care. lifestyle changes, prevention	Symptom Checklist-90 (SCL-90), Centre for Epidemiologic Studies Depression Scale (CES-D), health-related behaviours as smoking pattern, diet, physical activity (interview), BP, lipids, BMI
Sisk et al. 2006, USA	Education and management programme vs received guidelines for managing systolic dysfunction	Hospital, telephone	One nurse and one patient	Counselling , follow-up	Prevention, self-care	Hospitalization, Short Form-12 physical component score (SF-12), Minnesota Living with Heart Failure Questionnaire (MLHF), death
Baig et al. 2007, USA	Faith community nurse referrals vs telephone-assisted physician appointed intervention	Office in the church	One nurse and one patient	Screening	Prevention	Socio-demographic data, smoking status, (family) history of hypertension, other diseases, BP, medication, hypertension knowledge (MDRTC), Hypertension self-care (MDRTC)
Jiang et al. 2007, China	Rehabilitation programme vs unspecified routine care	Hospital and the home of the patient	One patient (and eventual family	Support, education	Self-care, lifestyle changes	Smoking cessation measure, Jenkins Activity Checklist for Walking, 3-day dietary record, self-reported drug compliance scale, serum lipid Body weight, and BP

			members) and one nurse			
Hanssen et al. 2007, Norway	Telephone follow-up intervention and open telephone line vs current clinical practice (one outpatient visit to a physician and subsequent visits to GP)	Telephone	One nurse and one patient	Information , support	QoL, lifestyle changes,	36 item Short Form Health Survey (SF-36), self-constructed questionnaire on life style
Malm et al. 2007, Sweden	Self-care programme vs specified standard check up	Hospital and telephone	One nurse and one patient (and spouse)	Education, information	QoL	Socio-demographic and clinical information from medical record, six-minute walk test, The one-and-a-half-minute stair test, Euro-QoL (EQ-5D), Psychological General Well-being Scale (PWBG), Subjective Consequences of Pacemaker Therapy (SCOP)
Shearer et al. 2007, USA	Telephone empowerment support vs nothing	Telephone	One nurse and one patient	Empowerment, counselling	Self-management, self-care	Socio-demographic data, the Power as Knowing Participation in Change Tool VII (PKPCT), Ware Short-Form Health Survival (SF-36), Self-management of Health Failure scale (SMHF)
Goodman et al. 2008, UK	Homecare support and education programme vs usual care (hospital helpline telephone and a pre-information day)	The home of the patient	One nurse and one patient	Counselling , education	Self-care, lifestyle changes, preparation for surgery, QoL	HAD Scale, BP, BMI, Cholesterol, change in smoking rates, blood glucose, Coronary Revascularization Outcome Questionnaire (CROQ), SF-36, post-operative complications
Jaarsma	Additional basis	Hospital	One	Support,	Cost-	Data on mortality, number of re-

et al. 2008, The Netherla nds	support by nurse vs intensive support by nurse vs follow-up by cardiologist		nurse and one patient	counseling, education	benefit, survival	hospitalization, history of disease(s) and medication, BP, blood tests.
Sherrard et al. 2009, Canada	Follow-up interactive voice call for screening of symptoms x 11 vs usual care consisting of interactive voice call for screening of symptoms x 2	The home of the patient	Compute r standard program	Screening	Prevention	Questionnaires about medication safety and symptoms, user satisfaction on the interactive voice call system
Zhao and Wong 2009, China	Transitional care programme vs routine discharge care involving attention point at home	Home visit and telephone	One nurse and one patient	Education, counselling	Self- managemen t, self-care	Demographic and baseline health assessment data; understanding of diet, medication exercise, health related life style, health care utilization and satisfaction with care (self- constructed)
Andryuk hin et al. 2010, Russia	Education programme in three parts: 1) group education on lifestyle 4 x 1½ h. 2) 4 x ½h introduction to exercise training. 3) Nurse consultation ½ min weekly in 5 month vs. usual care according to the	The clinic of GP and telephone	Nurse and 5-6 patients. Exercise training: physioth erapist and one patient. Nurse Consulta tion:	Education in self-care	QoL and self-care	New York Heart Association Class of CHF, BMI, waist circumference, 6-min walking test, biochemical parametres

	Russian national guidelines		nurse and one patient			
Smeulders et al. 2010, The Netherlands	Chronic disease self-management programme and usual care vs unspecified usual care	Hospital	Group of patients and one nurse	Empowerment	Self-management	General Self-efficacy Scale (GSES). Two subscales of Cardiac Self-Efficacy Questionnaire, Mastery scale by Pearlin & Schooler, Coping with Symptoms Scale, European Heart Failure Self-Care Behaviour Scale (EHFScBS), RAND 36-item Health Survey (RAND-36), Kansas City Cardiomyopathy Questionnaire (KCCQ), Hospital Anxiety and Depression Scale (HADS)
Goessens et al. 2006, The Netherlands	Nurse consultation and unspecified usual care (by GP) vs unspecified usual care (by GP)	Risk-factor management clinic	One nurse, one GP and one patient	Support, counseling	Life style changes, self-care, prevention	Blood tests (vascular risk factors), medication, age, sex, BP, Body mass index, smoking
Artinian et al. 2007, USA	Tele monitoring BP and usual care vs usual care (unspecified)	The home of the patient, computer and telephone	One nurse and one patient	Counseling, support	Prevention, self-care, lifestyle changes	BP, socio-demographic data, life style factors, medicalization, physical examination
Sol et al. 2007, The Netherlands	Risk factor management by nurse vs specified usual care	Hospital	One nurse and one patient	Counseling, support, motivation	Self-care, lifestyle changes	The adapted Diabetes mellitus type 2 self-efficacy scale, age, smoking history, HbA _{1c} , BP, lipid, BMI, other blood analysis, vascular disease history
Tonstad et al. 2007,	Individual education vs nothing	Hospital	One nurse and one	Counseling, support	Self-care, lifestyle changes	Clinical data, smoking and dietary habits, physical activity, BP, medication, blood tests, height, weight, pulse,

Norway			patient			
Amoako and Skelly 2007, USA	Psycho-educational telephone intervention vs unspecified usual care	Telephone	One nurse and one patient	Counselling, education	Self-care, lifestyle changes	Mishel Uncertainty in Illness Scale-Community Form, Summary of Diabetes Self-Care Activities, Problem Areas in Diabetes Survey
Kim and Jeong 2007, South Korea	Web-input, SMS support and outpatient control vs outpatient control	Computer/telephone, SMS	One nurse and one patient	Advice, support	Prevention, self-care, lifestyle changes	Demographic data, HbA _{1c} , FPG, 2HPMG,
Houweling et al. 2009, The Netherlands	Case-management by CNS vs internist	Hospital	One nurse and one patient	Consultation	Treatment and prevention, cost-benefit, patient satisfaction, QoL	HbA _{1c} , BP, lipid, BMI, other blood analysis, Short-form-36 Questionnaire (SF-36), the Type2 Diabetes Symptom Checklist (DSC-type2) Patients' Satisfaction with the Quality of Diabetes Care (PEQD), healthcare costs
MacMahon Tone et al. 2009, Ireland	Intensive nurse-led diabetes care vs specified standard diabetes care	Hospital	One nurse and one patient	Education, Support	Prevention	BP, blood glucose and other blood analysis
Hawkins 2010, USA	Videophone self-management education 1x12 weeks+1x3 month vs 1x6 month	Interactive session between clinic and the home of the patient	One nurse and one patient	Education, Support	Self-management, prevention, lifestyle changes	HbA _{1c} , lipid, BP, BMI, cognitive impairment (SPMSQ), knowledge about diabetes (DKT), Self-efficacy for diabetes self-management (8-items DES-SF)
Huizinga et al.	Telephone quarterly follow-up vs	Telephone	One nurse/oth	Blood glucose	Prevention, self-	HbA _{1c} , weight, self-constructed questionnaire on symptoms

2010, USA	telephone monthly follow-up vs unspecified usual follow up		er professional and one patient	control, Support	monitoring of blood glucose	
Nesari et al. 2010, Iran	Telephone follow-up vs no follow up after 3 day's self-care education programme	Telephone	Nurse and one patient	Follow-up	Self-care	HbA _{1c} , self-reported questionnaire about demographic data, disease and level of adherence to the therapeutic regime
Stone et al. 2010, USA	Home-based telemedicine support vs telephone calls	Interactive session between clinic and the home of the patient	One nurse and one patient	Prevention, support, education, medication	Self-management	HbA _{1c} , lipid, BP, weight, history of medication
Raje et al. 2007, UK	Telephonic consultation vs nothing	Telephone	One nurse and one patient	Advice	Symptom management, diet change	Disease history, including rectal bleeding
Chan et al. 2009, UK	GNP led follow-up with individual counselling vs unspecified usual care by GP	Nurse-led clinic	One nurse and one patient	Assessment, counselling, self-care	Prevention, lifestyle changes, patient satisfaction	Socio-demographic data, height weight, stimulants, ulcer healing drugs, Glasgow Dyspepsia severity scores (Gladys), Health Status Short Form (SH-12), an unspecified patient satisfaction questionnaire
Chow and Wong 2010, Hong Kong	Discharge planning and 6 week telephone follow up vs standard information and hotline service	Hospital and telephone	One nurse and one patient	Education, organization, support	QoL	The Kidney Disease Quality of Life Short Form (KDQOL-SF™)
Wong et	Unspecified Routine	Telephone	One	QoL,	Self-	Dialysis diet and fluid non-adherence

al. 2010, Hong Kong	care and Disease management programme vs unspecified routine care		nurse and one patient	symptom control, self-care	management	Questionnaire (DDFQ), Kidney Disease Quality of Life (KDQOL), La Monica-Oberst Patient Satisfaction Scale, symptoms control
Verschuur et al. 2009, The Netherlands	Follow-up home visits by CNS vs outpatient clinic follow-up	The home of the patient	One nurse and one patient	Follow-up, advices, support	QoL, patient satisfaction, cost-benefit	EuroQoL-5D, incl. EQ-VAS (overall self-rated health), EORCT QLQ-C30 questionnaire, EORTC QLQ-OES18, self-constructed patient satisfaction questionnaire, estimated full cost prices.
Kimman et al. 2010, The Netherlands	Telephone follow-up vs. hospital follow-up	Telephone	One nurse and one patient	Follow-up	Patient satisfaction	Ware's Patient Satisfaction Questionnaire III (PSQ III)
Espie et al. 2007, UK	Small group teaching based on CBT, 5 x 1 h vs unspecified usual treatment from GP	Local GP	Nurse and 4- 6 patients per group	Teaching	Self-care, QoL	Pittsburgh Sleep Quality Index, Hospital Anxiety and Depression Scale, Epworth Sleepiness Scale, structured sleep diary, actigraphs, hypnotic medication use, Short Form 36.
Elley et al. 2008, New Zealand	Home-based nurse assessment of falls-and-fracture risk factors and home hazards, referral to intervention vs unspecified usual care and social visits	The home of the patient	One nurse (and other professional if needed) and one patient	Screening followed by intervention	Fall prevention	Rate of falls, demographic and clinical data, Timed Up and Go Test, 30-second chair stand test, four-test balance scale, 7.5-cm block step test, Modified Falls Efficacy Scale, Nottingham Extended Activities of Daily Living Profile, Auckland Heart Study physical activity questionnaire, Medical Outcomes Study 36-Short Form Questionnaire

Harrison et al. 2008, Canada	Leg ulcer management at home vs nurse clinic	The home of the patient	One nurse and one patient	Wound care, QoL, patient satisfaction	Ulcer healing, durability of healing, time free of ulcers, QoL, patient satisfaction, cost-benefit	Guideline for healing assessment, Short Form Pain Questionnaire (SF-MPQ), SF-12, self-constructed satisfaction questionnaire, assessing the basic resource use for an episode of ulcer care
Dierick-van Daele et al. 2009, The Netherlands	Consultation by NP vs consultation by GP	GP practice	One nurse/GP and one patient	Consultation	Patient satisfaction/quality of care, health status, cost-benefit, consumption, compliance of practical guidelines	Self-constructed questionnaire, EQ-5D, demographic data and data on diagnosis and treatment from computer system, practical guidelines (Dutch College of general Practitioners)
Dumville et al. 2009, UK	Larval therapy vs standard debridement technique (hydrogel) for slough or necrotic leg ulcer	Hospital and the home of the patient	Nurse and patient	Wound care	Treatment, QoL	SF-12, Baseline and follow-up data on the wounds, bacterial load
Spice et al. 2009, UK	Nurse assessed risk factors and targeted referral to professionals in the community vs multi-	General practices and clinic in the community	One professional and one patient	Screening	Fall prevention	Baseline: Demographic information, Abbreviated mental test score, modified Barthel index, timed 'Get up and go' test, medical diagnoses, drug history, fall history, osteoporosis risk

	disciplinary assessment and appropriate interventions in day hospital vs unspecified usual care					Follow-up: fall history
ter Bogt et al. 2009, The Netherlands	Life-style intervention vs unspecified usual care by GP	Clinic and Telephone	One nurse and one patient	Instruction, Counselling	Prevention	Weight, length wait circumference, BP, blood analysis, smoker status, physical activity
Lamers et al. 2006, 2010, The Netherlands	Minimal psychological intervention and unspecified usual care vs unspecified usual care	The home of the patient	One nurse and one patient	Counselling , education	Self-management	Beck Depression Interventory (BDI), Physical Component Score (PCS), Mental Component Score (MCS) of the Short Form 36 (SF-36)
Ulm et al. 2010, Germany	Intensive care programme vs routine visits at GP	GP's clinic	One nurse and one patient	Disease control, advice on lifestyle change	Prevention, lifestyle change	BP, weight, psychical activity, tobacco smoking, alcohol consumption
Wearden et al. 2006, 2010, UK	Pragmatic rehabilitation vs Supportive Listening treatment vs GP usual treatment (unspecified)	Telephone	One Nurse and one patient	Support	QoL	Townsend deprivation index scores, Short Forms 26 (SF-36), Hospital Anxiety and Depression Scale (HADS)

Nathan et al. 2006, UK	30-min follow-up consultation by CNS vs by respiratory doctor	Hospital	One Nurse and one patient	Assessment, education, medication	Prevention, self-management, self-care	Peak flow, diary card for 6 month follow-up (medication change, emergency treatment, exacerbations, Asthma Questionnaire 20 Quality of Life (AQ20), St. George Respiratory Questionnaire (SGRQ))
Sridhar et al. 2008, UK	Pulmonary rehabilitation vs unspecified care from GP/nurse	Hospital, the home of the patient and telephone	Groups of patients/ one patient and one nurse	Education	Prevention, QoL	Chronic Respiratory Questionnaire, hospital readmission rate, unscheduled primary care consultations
Willems et al. 2008, The Netherlands	Tele-monitoring programme vs unspecified regular outpatient care	Internet and telephone	One Nurse and one patient	Symptom management	QoL, self-management	(Paediatric) Asthma Quality of Life Questionnaire ((P)AQLQ), diaries of clinical asthma symptoms and medical consumption, lung function parameters (PEF, FEV1)
Antic et al. 2009, Australia	Home-based simplified nurse-led model of care vs two laboratory polysomnograms to diagnose and treat OSA, with clinical care supervised by physician	Hospital	One nurse and one patient	Consultation, management	QoL, sleep patterns, Patient satisfaction	Epworth Sleepiness Scale (ESS), Short-form 36 Health Survey (SF-36), Functional Outcomes of Sleep Questionnaire (FOSQ), Executive Neurocognitive function, Maintenance of Wakefulness Test (MWT), Visit-specific Satisfaction Questionnaire (VSQ-9)
Vitacca et al. 2009, Italy	Tele-assistance care programme vs specified usual outpatient follow-up	Interactive session between clinic and the home of the	One nurse and one patient	Consultation, counselling	Treatment, Prevention, self-care, cost-benefit	Clinical Score System Respicard, pre-morbidity lifestyle score, respiratory function, diseases, mortality, exacerbations, hospitalization, contact to healthcare

		patient				professionals, medication
Lamers et al. 2010, The Netherlands	Minimal psychological intervention vs usual care according to the clinical guidelines for the treatment of COPD of the Dutch College of GPs	The home of the patient	One nurse and one patient	Counselling, therapy	Self-management	Beck Depression Inventory (BDI), Symptom Checklist-90 (SCL), PHQ-9 screening, Saint George's Respiratory Questionnaire (SGRQ)
Van der Meer et al. 2009, 2010, The Netherlands	Internet based self-management algorithm vs asthma care according to the Dutch GP guidelines	Internet and telephone	Professionals and patient	Managing asthma, advising	Self-management	Asthma Control Questionnaire(ACQ) score, Asthma Therapy Assessment Questionnaire (ATAQ) Control Index
Ryan et al. 2006, UK	Consultation according to Pendelton's seven task by CNS vs outpatient consultation by clinical nurse	Hospital	One nurse and one patient	Consultation, monitoring, medication	Self-care, QoL, cost-benefit	Arthritis Impact Measurement Scale (AIMS), Rheumatology Attitude Index (RAI), Disease Activity Score (DAS), disease history, socio-demographic data, use of healthcare professionals
Hill et al. 2009, UK	Case management by CNS vs Case management by JHD	CNS clinic	One professional and one patient	Consultation, treatment	Patient well-being, patient satisfaction, painlessness, self-efficacy	Pain assessment by visual analogue scale, Arthritis Self-Efficacy Scale (ASES), AIMS, Patient knowledge questionnaire-osteoarthritis (PKQ-OA), Leeds Satisfaction Questionnaire (LSO)

QoL=Quality of Life, HRQoL= Health-related quality of life, AMI=acute myocardial infarction, SPB=Systolic blood pressure, LOS=length of

hospital stay, BP=Blood Pressure, BMI=Body Mass Index, CNS=clinical nurse specialist, NP=Nurse Practitioner, GP=General Practitioner, CBT=cognitive behavioral therapy, COPD=Chronic Obstructive Pulmonary Disease, BP=blood pressure, JHD=junior hospital doctor.